

Will my GP be informed if I decide to take part?

Yes, with your permission, to let them know that you are taking part in WILL.

What might be the benefits and risks of taking part?

Planned early term birth *may* decrease health problems for you, decrease Caesarean birth, and either decrease some problems (like stillbirth) or increase others (like initial breathing difficulty) for your baby. However, it is possible that there will be no benefit at all. Although, the knowledge that we gain from this research, *with your help*, might in the future benefit many women with high blood pressure in pregnancy by determining the best timing of birth.

Who are we?

Our research team is very experienced. The Chief Investigator is Laura Magee, who is a Professor of Women’s Health at King’s College London. The trial is run by the Birmingham Clinical Trials Unit.

WILL is funded by National Institute of Health Research. The study is sponsored by King’s College London and Guys and St Thomas’ NHS Foundation Trust.

How do I learn more about the study?

Our contact details are listed below. We are happy to provide you with any additional information or answers to any questions that you may have.

Contact us

INSERT LOCAL TRUST CONTACT DETAILS

Chief Investigator:

Professor Laura A. Magee

WILL Trial Office:

Birmingham Clinical Trials Unit

Tel: 0121 415 9109

Email: WILL@trials.bham.ac.uk

Website: www.birmingham.ac.uk/will



The WILL Trial
Introductory pamphlet
(for women who may be interested in participating in the WILL Trial)



When to Induce Labour to Limit risk in pregnancy hypertension – a multicentre, randomised controlled trial

(Version 2.0 5th November 2020)
IRAS: 252294

Thank you for taking time to read this pamphlet which will explain briefly about the WILL Trial.

What is the WILL Trial investigating?

WILL aims to find out, for women with high blood pressure in pregnancy, the best timing of birth once 'term' is reached, which starts at 37 weeks and zero days (37⁺⁰ weeks) of pregnancy.

What is the background to WILL?

There is limited information to help us time birth for women who have high blood pressure in pregnancy. Maternity care guidelines and clinical practice vary between hospitals, even within the NHS.

Currently, women with high blood pressure who reach term gestational age await onset of spontaneous labour until they reach at least 40 weeks, unless you develop a problem that means you need to give birth to your baby earlier.

Why is high blood pressure in pregnancy a concern?

High blood pressure in pregnancy can be a risk to both mother and baby.

If you have high blood pressure during your pregnancy, this pamphlet will tell you about the WILL Trial. We hope that you will be interested in finding out more and possibly taking part.

Who can take part?

WILL is open to any woman who is at least 16 years of age, who has high blood pressure in pregnancy, and who is being cared for at a hospital in the UK.

Exceptions are women who:

- have *very high* blood pressure until it is better controlled;
- are carrying a baby with a major problem that doctors think is likely to require admission to a neonatal care unit after birth;
- are already participating in a study that is looking at the timing of birth; or
- have already participated in the WILL Trial.

Are there any tests that must be done before I can participate?

No. All we need to know to assess whether you can participate in WILL is available as part of routine antenatal care.

Do I have to take part?

No. Participation is entirely up to you. Whether or not you decide to participate will not affect your care or the care of your baby.

What will participating involve?

We will invite you to participate when you are 36⁺⁰ to 37⁺⁶ weeks. If you are eligible and interested in participating, you will be asked to give your consent. At 37⁺⁰ to 37⁺⁶ weeks, you will be allocated randomly by a computer system to one of two timing of delivery groups:

- **Planned early term birth:** When you are 38⁺⁰ to 38⁺³ weeks, your doctor or midwife will arrange a date to start off your labour (induction of labour) or perform an elective Caesarean if that is already your plan).
- **Expectant care at term (until at least 40 weeks):** You will continue to receive normal antenatal care while you are waiting for labour to start, and your baby's birth will be planned for when you reach at least 40 weeks unless you develop a problem that means you need to give birth earlier. This is the same as normal NHS maternity care that you would receive if not enrolled in WILL.

Your research midwife will contact you weekly from consent until birth. After birth, s/he will provide support needed to complete two questionnaires.

(1) Before leaving hospital, you will be asked to complete a short questionnaire about the experience of the birth of your baby.

(2) At 6 weeks after birth, you will be sent, via text message, a link to a brief online questionnaire, asking about any health problems that you or your baby may have had since leaving hospital after birth.